

KEMENTERIAN KESIHATAN MALAYSIA INSTITUT PENYELIDIKAN KLINIKAL





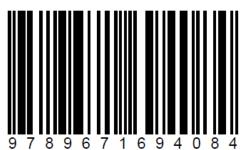
Celebrating
the past,
Embracing the
future

YEARS OF EVOLUTION: FROM NCRC TO ICR



Institute for Clinical Research

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Foreword

Minister of Health

Affordable healthcare driven by data and science is fundamental for ensuring better population health outcomes and better quality of life. Research can improve equity by increasing healthcare access, addressing unmet needs, and providing personalised novel therapeutics. This is where the Institute for Clinical Research (ICR)—established to meet the clinical research needs of the Ministry of Health (MOH) Malaysia—is driving clinical research of benefit to patients.

Clinical research excellence propelled by ICR continues to not only inform MOH's decision-making but also provide evidence to improve health outcomes for practice translation. The recognition accorded to ICR through impactful research has placed Malaysia on the global map for researchers—from industry and academia—to pursue collaborative research linked to clinical trials.

From the first Clinical Research Centre (CRC), formally established in 2000, ICR's network of CRCs is now at 37. Remarkably, two sites are accredited by international standards to be able to conduct First-in-Human clinical trials. Such is an attestation to MOH's commitment to building research infrastructure and human capital to sustain a resilient clinical research ecosystem for the nation.

This book captures a glimpse into an institutional force within the MOH. In the decades ahead, I hope for ICR to strive for excellence by enhancing capacity building, transforming the healthcare ecosystem with evidence-based recommendations, capitalising on digital healthcare advancements, and addressing the needs of research in Malaysia.



Foreword

Director-General of Health



The Ministry of Health (MOH) healthcare system integrates research evidence to provide high-quality treatment centred on value-based medicine and data-driven clinical decision pathways. Research by the Institute for Clinical Research (ICR), National Institutes of Health (NIH) Malaysia and its Network of 37 Clinical Research Centres (CRCs) has contributed to MOH policy-making and practice guidelines for better patient outcomes. The Ministry takes pride in the ICR for developing clinical research training and standards, global research collaborations, and prestigious research publications—all accomplished in such a short time.

On behalf of the Ministry of Health, I express my gratitude to past and current directors, lead clinicians, and researchers at ICR and CRCs for their dedication to advancing clinical research in Malaysia and driving research that matters to patients.

This book serves as a record of how ICR has evolved and grown over time and a testament that perseverance breeds success. Congratulations to ICR for 22 years of accomplishments. We look forward to ICR continuing to advance excellence in research in the coming years.

Message

Deputy Director-General of Health (Research and Technical Support)

My journey with Institute for Clinical Research, ICR (previously called National Clinical Research Centre, NCRC) began as the Head of CRC Hospital Sultanah Bahiyah Alor Setar established in 2006. I feel honored to be part of the evolution from NCRC to ICR over the past two decades.

Housed within the National Institutes of Health (NIH), ICR and five other research institutes lead the research endeavours of the Ministry of Health Malaysia. Championing clinical research, ICR has impacted clinical practice to bring forth betterment in health outcomes. Through the expansion of its own Network of CRCs and extensive collaborative strength, ICR has become a clinical research force within NIH and the nation.

I congratulate ICR for producing this book that records the essence and achievements of ICR. May the readers be inspired by the story of ICR and may it spark enthusiasm and motivation among researchers to excel in their research undertakings.

My hope is that, as one of the institutional pillars of the NIH, ICR continues on an upward trajectory in contributing to patient and population health.



Datuk Dr. Muhammad Radzi Bin Abu Hassan

Message

Manager National Institutes of Health (NIH)



Under the umbrella of the National Institutes of Health (NIH), six research institutes including the Institute for Clinical Research (ICR) operate as the research arm of the Ministry of Health Malaysia. Each research institute strives for impactful research on their focus areas that propagates evidence-based medicine with the aim to enhance the health and well-being of the nation.

The COVID-19 era is a testament to the strength of all research institutes at NIH to produce timely and meaningful scientific evidence that guides health policy and practice. Notably, research led by ICR generated evidence to inform COVID-19 clinical management and immunisation policies. Given the growth that has been achieved, I envision that each NIH research institute will continue to strengthen itself and each other to raise NIH as a research powerhouse in Malaysia.

This book documents the evolution of what now stands as ICR and its commendable achievements over the past two decades. I earnestly congratulate ICR supported by the Network of Clinical Research Centres for nurturing the nation's clinical research ecosystem to its current flourishing state. I hope this book inspires existing and aspiring researchers in developing themselves and their skills in research.

Dr. S. Asmaliza Binti Ismail

Message Director

Director Institute for Clinical Research (ICR)

It gives me great pleasure to introduce Years of Evolution: from National Clinical Research Centre (NCRC) to Institute for Clinical Research (ICR) in conjunction with the 22nd anniversary of the Institute's establishment. The leadership, contribution, and dedication of ICR's leaders, clinicians, researchers, and staff are recognised and commemorated within these pages. By applying attentive leadership strategies, formulating essential and effective quality standards, creating strong human research capacity, as well as setting up accredited research infrastructure, ICR is continually spearheading excellence in the Ministry of Health (MOH) Malaysia's research ecosystem.

In the early years, ICR initiated several national clinical registries, pioneered the establishment of the National Medical Research Register (NMRR), and created a historic underpinning of research that led to access to affordable trial medication for hepatitis C patients. Since its start two decades ago, ICR has achieved remarkable progress. There are now 37 Clinical Research Centres in MOH hospitals involved in clinical research for the development of new treatments and medications for diseases and conditions. The COVID-19 pandemic also witnessed key research recognition for ICR's involvement in WHO Solidarity Trial, I-TECH Study (Ivermectin), Vaccine Trials (IMBCAMS, Sinovac Biotech, Livzon, Cansino Bio), the utilization of digital health technologies such as CODIQ-My and Cof'e App, as well as nationwide policy-driven vaccination research including RECoVaM, VIGILANCE, and SafeCoVAC.

The future remains bright as we look forward to the implementation of Precision Medicine and Digital Health Innovative solutions, as well as becoming a regional hub for First-in-Human clinical trials. As part of the global ecosystem, ICR will strive continuously to be at the forefront of clinical research in providing knowledge to improve care for patients and deliver better healthcare for the population.



Datuk Dr. Kalaiarasu M. Peariasamy



"If I have seen further than others, it is by standing upon the shoulders of giants."

—Sir Isaac Newton



ICR IS ONE OF SIX RESEARCH INSTITUTES UNDER NIH-THE RESEARCH ARM OF MINISTRY OF HEALTH MALAYSIA

THE ICR EVOLUTION

2000

1997

Clinical Research
Centre (CRC) founded
by Tan Sri Dato' Seri
Dr. Ismail Merican to
ensure quality and
ethical conduct of
clinical research in
Ministry of Health
(MOH) Malaysia.

The first fully operational CRC formally established at Hospital Kuala Lumpur.

2001-2002

Three original units initiated under CRC:

- Clinical
 Epidemiology
 Unit
- Evidence-Based
 Medicine Unit
- Clinical Trial
 Unit

2003-2009

- Formation of 14 CRCs (Network of CRCs) under CRC headquarters (National CRC, NCRC).
- NCRC + The Network of CRCs incorporated as a research institute under the National Institutes of Health (NIH) MOH Malaysia.
- NCRC established
 Healthcare Statistics Unit in 2009.

2011-2018

Continued growth of The Network of CRCs nationwide.

2019

- NCRC rebranded as Institute for Clinical Research (ICR) under NIH, Setia Alam.
- Four centres
 established under ICR
 (rebranding of three
 units and creation of a
 new centre): CCE,
 CCORe, CCT, CCRN
- The Network of CRCs continued to be within the purview of ICR.

2020-2022

- ICR established
 Digital Health
 Research and
 Innovation Unit
 (DHRi) in 2020.
- Continued growth of The Network of CRCs nationwide totaling 37 CRCs in 2022.

Way Forward

Future research focus:

- Precision medicine
- Digital health
- Clinical trial
 hub

Economic Area in creating a supportive ecosystem to grow clinical research

2010

• CRC recognised under the

Healthcare National Key

- alongside Clinical Research Malaysia (CRM).
- The Clinical Trial Ward under the Clinical Trial Unit was established at Hospital Ampang.
- CRC established early phase and bioavailability/ bioequivalence clinical studies within MOH facilities.



Vision

To Become a Leading Clinical Research Institution in Asia

Mission

To Improve Patients' Health Outcomes
Through Ethical and Quality Clinical Research



The Mat Metwork o **NORTH** • Hospital Tuanku Fauziah • Hospital Sultanah Bahiyah • Hospital Sultan Abdul Halim Hospital Pulau Pinang • Hospital Seberang Jaya Hospital Taiping • Hospital Seri Manjung • Hospital Raja Permaisuri Bainun **EAST COAST CENTRE** Hospital Tengku Ampuan Afzan Hospital Sultanah Nur Zahirah • Hospital Kuala Lumpur Hospital Raja Perempuan Zainab II Hospital Tunku Azizah Hospital Rehabilitasi Cheras Hospital Selayang • Hospital Sungai Buloh Hospital Ampang Hospital Tengku Ampuan Rahimah • Hospital Shah Alam Hospital Serdang • Hospital Putrajaya Institut Kanser Negara ICR, NIH SOUTH Centre for Clinical Epidemiology (CCE) • Centre for Clinical Outcome Research (CCORe) Hospital Tuanku Ja'afar Centre for Clinical Trial (CCT) Hospital Tuanku Ampuan Najihah Centre for Coordination of Clinical Research Network (CCRN) Hospital Melaka Digital Health Research and Innovation Unit (DHRi) Hospital Pakar Sultanah Fatimah **Hospital Sultanah Aminah Hospital Sultan Ismail**





Support and facilitate clinical research activities by identifying a pool of researchers and providing facility as well as administrative and technical support.

Assist in the registration of research protocols to the National Medical Research Register (NMRR) and application of research grants.

Functions of The Network of CRCs

Participate in clinical trials and other research initiated or coordinated by ICR.

Penyelidikan

Promote research through capacity building in the following ways:

- Good Clinical Practice (GCP)
- Good Research Practice (GRP)
- Continuous Professional Development (CPD) activities
- Research clinics
- Mentoring programme

ICR STRATEGIC PLAN (2020-2025)

STRATEGIC OBJECTIVES

To be the preferred clinical research hub

To establish a conducive digital research ecosystem



that generates
renowned
clinical
research
leaders

To be

recognised as

an institute



To be recognised as a trusted evidence-based medical information source for all



STRATEGIC PILLARS

Clinical Research Excellence

Technology in Clinical Research

Sustainable
Human
Capacity
Building

Visibility





YBhg. Dato' Dr. Zaki Morad Bin Mohamed Zaher DIRECTOR, NCRC (2000-2006)

"The establishment of NCRC came at an opportune time. Many clinicians were keen to do clinical research but lacked the necessary support required to do so. Many have difficulty drawing up proper research proposals. There were no dedicated staff to help them and most who embarked on clinical research relied on untrained ward/clinic nurses to collect data.

The priority of NCRC then was to set up basic infrastructure, selection and training of dedicated staff, and developing guidelines and SOPs. With the help of a number of dedicated individuals, we managed to do so in a relatively short time. We assisted doctors to participate in industry-sponsored trials that exposed them to the rigours and discipline of conducting clinical trials.

It is gratifying to see the early NCRC which was housed in an office space in Hospital Kuala Lumpur developed into a large well-equipped and well-staffed facility that has taken us into the competitive world of clinical research."



Institu

Dr. Lim Teck Onn DIRECTOR, NCRC (2007-2010)

"The launch of The Network of Clinical Research Centres to coordinate clinical research within the Ministry of Health facilities via a single point of contact was an exciting time.

The way forward is to look towards growing Malaysia's own expertise in all clinical research-related fields. Human capacity development remains at the root of success. Opportunities abound for clinical research expertise in data management, statistical analysis, logistics, IT applications, systems security, sample handling, and other aspects along the clinical trial process.

In clinical research, the entire world stands to benefit. Congratulations, ICR! The future is waiting."



YBhg. Dato' Dr. Goh Pik Pin DIRECTOR, NCRC/ICR (2010-2020)

"Coming after the two giant clinician researchers, i.e. Dato' Dr. Zaki Morad and Dr. Lim Teck Onn, the first and second director of NCRC, who paved a solid foundation, my task to expand The Network of CRCs at various MOH hospitals became easier.

The high-quality clinical research conducted by MOH staff has provided sound evidence that helps improve healthcare programme and policy for the betterment of our community. This is clearly shown from the clinical research done during the COVID-19 pandemic under the leadership of the current director, Datuk Dr. Kalaiarasu M. Peariasamy.

My aspiration is to see ICR be empowered to provide necessary scientific exposure and support to MOH medical professionals who want to excel in both clinical work and research, especially now that ICR is housed in the well-resourced National Institutes of Health."



Institu

YBhg. Datuk Dr. Kalaiarasu M. Peariasamy DIRECTOR, ICR (2020-PRESENT)

"ICR possesses the heart of a powerful research tool by combining strong human research capacity, patient centricity, innovative intuitions, and digitally-enabled solutions thereby continuing to lead and support higher enrolment, wider engagement, and high-quality healthcare. These will remain essential in realising our ambitions to make ICR a regional hub for clinical research—improving patient health outcomes and making a tangible difference to patients' lives."

THE GROWTH OF TH

YBhg. Dato' Dr. Zaki Morad Bin Mohamed Zaher

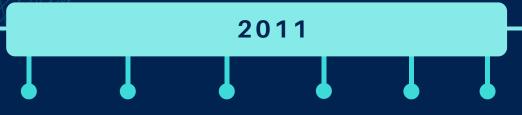
(2000-2006)

YBhg. Dato' Dr. Goh Pik Pin

(2010-2020)

2003 2006

- Hospital Pulau Pinang
- Hospital Umum Sarawak
- Hospital Tengku Ampuan
 Afzan
- Hospital Sultanah Bahiyah
- Hospital Selayang
- Hospital Tuanku Ja'afar



- Hospital Queen Elizabeth II
- Hospital Wanita dan Kanak-Kanak Sabah
- Hospital Seri Manjung
- Hospital Seberang Jaya
- Hospital Taiping
- Hospital Sibu



- Hospital Kuala Lumpur
- Hospital Miri
- Hospital Sultan
 Ismail
- Hospital Duchess of Kent
- Institut Kanser
 Negara
- Hospital Sultan
 Abdul Halim
- Hospital Rehabilitasi Cheras
- Hospital Pakar
 Sultanah Fatimah

E METWORK OF GRG



- Hospital Tuanku
 Fauziah
- Hospital Raja
 Permaisuri Bainun
- Hospital Ampang
- Hospital Sultanah
 Nur Zahirah
- Hospital Raja Perempuan Zainab II
- Hospital Sultanah Aminah

Dr. Lim Teck Onn

(2007-2010)



- Hospital Serdang
- Hospital Putrajaya
- Hospital Sungai Buloh
- Hospital Melaka
- Hospital Queen Elizabeth



- Hospital Tengku
 Ampuan Rahimah
- Hospital Shah Alam
- Hospital Tunku Azizah
- Hospital
 Tawau
- Hospital
 Bintulu
- Hospital Tuanku Ampuan Najihah

YBhg. Datuk Dr. Kalaiarasu M. Peariasamy

(2020-Present)



Centre for Clinical Epidemiology (CCE)

The mission of CCE is to contribute evidence through epidemiological research to bridge the gaps between clinical practice and health policy in the best interest of patient care.

As one of the main arms of the Institute for Clinical Research, we undertake multidisciplinary scientific research on disease prevention, occurrence, treatment, and prognosis.



Detection, Diagnosis, and Cancer Treatment
Timeline in Malaysia (DEDICATE) Study:
Presentation to stakeholders, November 2019



Humoral Immunity Response of BNT162b2 mRNA Vaccination Among Healthcare Workers in Malaysia (VIGILANCE) Study: Data collection, August 2021



CCE team

Centre for Clinical Outcome Research (CCORe)

Formerly known as Healthcare Statistics Unit (HSU).

Aim: to become a leading centre in evaluating and improving clinical and health outcomes through impactful research.

Research focus areas: PRIMARY CARE and CARDIOVASCULAR RESEARCH

CCORe members are formally trained in public health, data analytics, pharmacoepidemiology, implementation research, and systematic review.

2009-2014

NHSI

National Healthcare Establishment & Workforce Survey

National Medical Device Survey

National Medicine Utilisation Survey

National Medical Care Survey

GOLD AWARD The RECOVAM Study Group
Dr. Masliyana Husin, Suah Jing Lian
Datin Dr. Sheamini Sivasampu
Dr. Peter Tok Seah Keng, Dr. Tng Boon Hwa
Thevesh Thevananthan
Datuk Dr. Kalaiarasu M Peariasamy and Collaborators for Clinical Research, National Institutes of Health, Ministry of Health Malaysia ovation In Data Practices For COVID-19 Vaccine ectiveness Research (The RECoVaM Study Group Government & Policy

2015-2016

MHSR

Quality and Outcome Framework (QOF)

Cost Function and Efficiency

Quality and Costs of Primary Care (QUALICO-PC)

Amenable Mortality



MHSR: Enhanced Primary Health Care (EnPHC)

Stroke Metrics & Treatment

Heart Failure Metrics

Zika Case Series

Dengue HLH



Barriers to Hyperacute Stroke

Teleconsultation in Primary Care

RCTs: Tocilizumab, Favipiravir/Ivermectin

COVID-19 Vaccine Surveillance:

RECoVaM, VIGILANCE, and SafeCoVAC.

Long COVID cohort (LOCOVIM)





Centre for Clinical Trial (CCT)

Established in 2010.

Conduct and support all phases of clinical research, bioavailability, and bioequivalence studies in accordance with local and international standards.

Bridge the gap from bench to bedside by conducting Phase 1 Clinical Trial.

Support the local generic pharmaceutical industry by conducting bioequivalence studies to allow the availability of more cost-effective medication.

DNDi-SOF/RDV-01-HCV Study (hepatitis C study): Improve drug affordability and accessibility from USD\$100,000.00 to USD\$300.00





CanSino Vaccine Clinical Trial:
The World's First Inhaled Vaccine Trial

NPRA Phase 1 inspection visit 2022: CCT Ampang was accredited as a Phase 1 site on 11th January 2022



Centre for Coordination of Clinical Research Network (CCRN)

TRAINING



- Good Clinical Practice Secretariat for MOH
- Conduct Research Training





CONSULTATION



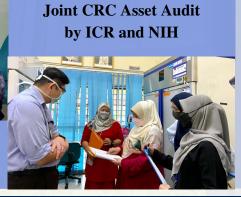
Research Consultation Clinic

GOVERNANCE

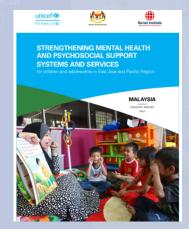
Coordinate Research Management for The Network of 37 CRCs



Mock Survey MSQH Standard 26: CRC



RESEARCH







Strengthening Mental Health and Psychosocial Support (MHPSS) Systems and Services for Children and Adolescents in East Asia and Pacific Region 2022

Digital Health Research and Innovation Unit (DHRi)

Established in 2020.

Dedicated to drive research and innovation in digital health.



FUNCTION

- Drive digital health research and transformation in the healthcare sector.
 - Boost the competitiveness of ICR through collaborative digital health research.
- Build and enable digital health infrastructure.
- Nurture agile and competent digital health talents.



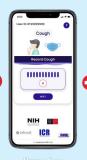




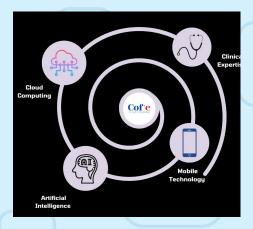












Cof'e is the latest COVID-19
pre-screening digital solution
developed by DHRi.
The solution incorporates
mobile technology, cloud
technology, clinical
expertise, and A.I. to help the
public to detect COVID-19
infections anytime and
anywhere with no additional
cost.



CRC HOSPITAL TUANKU FAUZIAH



Established in May 2007

GOOD COLLABORATION with local universities:

i. Universiti Malaysia Perlis (UniMAP)

ii. Universiti Teknologi MARA (UiTM)

iii. Universiti Utara Malaysia (UUM)



Protocol Development Workshop 2022

CRC HOSPITAL SULTANAH BAHIYAH

Established in 2006

Centre of Excellence for GASTROENTEROLOGY and HEPATOLOGY research, focusing on hepatitis C, NAFLD, and colorectal cancer





We are so happy for the patients. They have been waiting for a treatment for so long. Now, we can tell them: I have the treatment for you right now.

 $\mathsf{DND}i$

#hepatitisC

First Hepatitis C treatment developed through South-South cooperation registered in Malaysia



World
Hepatitis Day 2022
Screening Activity

ICR Award

CONGRATULATION

CRC Hospital Sultanah Bahiyah

Highest Publication Award





Established in 2015



TOP RECRUITER award

Dr. Vijaya Kumar

COVID-19 vaccine study

(enrolled 1500+ subjects)



CRC HOSPITAL PULAU PINANG



Top MOH Clinical Trial Site Award



CRC Penang booth during NCCR 2015



Good Clinical Practice 2022

22 YEARS OF ICR EVOLUTION

CRC HOSPITAL SEBERANG JAYA

Established in 2011



Centre of Excellence for STROKE and DEMENTIA research



Accredited BABE centre by the National Pharmaceutical Regulatory Agency

Equipped with a 24-bedded Clinical Trial Unit (CTU) ward

CRC HOSPITAL TAIPING

Established in 2011



Research focus areas:
GERIATRIC, PUBLIC HEALTH,
PHARMACOEPIDEMIOLOGY, and PHARMACY

2015: CRC with the highest number of publications

PLEDGE study: enrolled the first patient in Malaysia

LIVZON-V01 study: First site in Malaysia to reach recruitment target



Taiping
Research Day 2020





Dr. Lee Li Yuan

- TOP RECRUITER for 7 studies (2013–2021)
- 6th GLOBAL HIGHEST RECRUITER in 2017

CRC HOSPITAL RAJA PERMAISURI BAINUN

Established in 2007



Well-balanced multidisciplinary research team

Perak Medical Journal

- Collaboration with the Postgraduate Medical Education Society Hospital Raja Permaisuri Bainun
- Digital journal publishing research articles by researchers in Perak

Impactful Research:

Improving Management of Prolonged Neonatal Jaundice (NNJ) in a Regional Setting: an Interventional Quasi-Experimental Study. Adapted into MOH Integrated Plan for NNJ Detection and Management

National Childhood Drowning Registry

Escalator Safety Among Children

Impact of Electronic Screens on Speech Development of Children

Is Ipoh an Age-Friendly City? A Mixed-Method Study Exploring the View of the Elderly and Their Caregivers

CRC HOSPITAL KUALA LUMPUR



Established in November 2012

'PRIME SITE' for Industry-Sponsored Research (ISR) by IQVIA since 2014

SITE ALLIANCE MEMBER under the collaborative work with PARAXEL since November 2016

Clinical Trial Unit functioning since 2019

Annual HKL Research Day



CRC HOSPITAL TUNKU AZIZAH



Clinical research
hub for
PAEDIATRICS and
OBSTETRICS &
GYNAECOLOGY

Coordinates inter-agency collaborations in clinical research and innovation projects

CRC HOSPITAL REHABILITASI CHERAS



Established in 2015

Focusing on REHABILITATION MEDICINE

Collaborations:

- Universiti Teknologi Malaysia (UTM) for 3D printing
- SIRIM Berhad
 to produce 3D-printed prostheses sockets for rehab patients



CRC HOSPITAL SELAYANG



First CRC in Selangor

Established in 2006

Trial hub for NEPHROLOGY, HEPATOLOGY, RHEUMATOLOGY, DERMATOLOGY, OPHTHALMOLOGY, and UROLOGY

One of the earliest CRCs equipped with calibrated clinical trial equipments

Top hospital for high cumulative ISI Impact Factor per researcher



CRC HOSPITAL SUNGAI BULOH



Established in 2010



Centre of Excellence for INFECTIOUS DISEASE research

Numerous COVID-19 research and publications 2020–2022



CRC HOSPITAL AMPANG



Established in 2007



Centre of Excellence for **HAEMATOLOGY** research

Top recruiter of Phase 1 Cyto-MSC trial

CRC HOSPITAL TENGKU AMPUAN RAHIMAH



Established in 2006

2016: CRC with the highest number of publications

Research focus areas:

ANAESTHESIA and PAIN MANAGEMENT



CRC HOSPITAL SHAH ALAM



Established in 2016

Centre of Excellence for OPHTHALMOLOGY research

Advanced medical technology equipment in the Ophthalmology department



CRC HOSPITAL SERDANG

Established in 2010

Centre of Excellence for CARDIOLOGY and NEPHROLOGY research



CRC HOSPITAL PUTRAJAYA



Established in 2010

Centre of Excellence for ENDOCRINOLOGY research



CRC HOSPITAL WANITA DAN KANAK-KANAK SABAH



Established in February 2011

Research focus areas:

- **Obstetrics**
- GynaecologyPaediatrics

Dr. Flora Chong Li Tze

First recruitment in Malaysia for multiple studies:

- GATSBY Study
- Everexes Study
- Jacob Study
- METGASTRIC Study

CRC INSTITUT KANSER NEGARA



Established in 2014



Centre of Excellence for ONCOLOGY research



2018:

Clinical Trial site of the year



Collaboration with pharmaceutical agencies e.g. Astra Zeneca:

- DESTINY trial on lung cancer
- SERENA-4 trial on breast cancer



CRC HOSPITAL TUANKU JA'AFAR



- O1 Established in September 2006
- **02** CRM-featured site 2022
- **03** Research focus areas:
 - Rheumatology
 - Nephrology
 - Paediatrics
 - Endocrinology
 - Psychiatry
 - Gastroenterology
- **04** Annual Seremban Research Day

TOP RECRUITER site in 2016 & 2017

CRC HOSPITAL SULTAN ISMAIL





Established in 2012



Support and facilitate research activities in the hospital:

- Provide databases
- Track ISR and IIR for publications
- Offer research management and technical support

CRC HOSPITAL TENGKU AMPUAN AFZAN

- **01** Established in 2003
- **O2** TOP RECRUITER in Malaysia and Asia Pacific region
- O3 DNDi Hep C project 2018 leadership award
- **04** CANOPY-1 study

Centre of Excellence for GASTROENTEROLOGY, NEPHROLOGY, and ONCOLOGY research



CRC HOSPITAL TUANKU AMPUAN NAJIHAH



Established in January 2022

CRC HOSPITAL PAKAR SULTANAH FATIMAH



Established in 2014

Good Clinical Practice(GCP)



Statistics Workshop

CRC HOSPITAL MELAKA



Established in 2007

Active in Investigator-Initiated Research

Renowned Research: MAVERIK, WHO SOLIDARITY, I-TECH, TECOS, CLARIFY

CRC HOSPITAL SULTANAH AMINAH

Established in 2007







Training:

- Good Clinical Practice (GCP)
- Introduction to Clinical Research (ICR)
- Research methodology
- Critical appraisal and evidencebased medicine
- Biostatistics

Johor Research Day 2018



CRC HOSPITAL UMUM SARAWAK



in 2003

One stop three-floored clinical trial facility



Dedicated
Phase 1 Unit

Established

Accredited Clinical Research Laboratory:

- MS ISO/IEC 17025: 2017 (chemical testing)
- MS ISO 15189: 2014 (medical testing)





Numerous First-Patient Awards Locally and Globally

CRC HOSPITAL SULTANAH NUR ZAHIRAH

CRC HOSPITAL RAJA PEREMPUAN ZAINABII

- Established in 2007
- National Neurology Registry (NNeuR)



Centre of Excellence for **NEUROLOGY** research

Collaborators:

- i. Universiti Sains Malaysia's School of Medical Sciences
- ii. London School of Hygiene and Tropical Medicine



Research focus areas:

- Cardiology/Vascular Diseases
- Endocrinology
- Gastroenterology
- Nephrology



- Established in 2007
- Paraxel Site
 Alliance



CRC HOSPITAL BINTULU

Established in 2020



Enhance research activity among the hospital staff and provide support to the researchers

CRC HOSPITAL QUEEN ELIZABETH



- Dermatology
- Gastroenterology
- Infectious Disease
- Nephrology
- Established in 2008
- for extensive contribution in MALARIA research
- Potential clinical trial hub for **Traditional and Complementary Medicine**

CRC HOSPITAL MIRI

Established in 2012



- 1. Significant Advancement Award for Site
- 2. Significant Investigator
 Award

Clinical Trials Day and Sponsored Research Award Presentation 2022

Northern Zone Sarawak Research Day



CRC HOSPITAL SIBU



Established in January 2011



Molecular test facilities established in partnership with SEGi University and Duke University in June 2017

Dr. Toh Teck Hock (Head of CRC)

1.RESPIRE study

- **GLOBAL TOP 5th** recruiter
- TOP RECRUITER outside Europe
- 2. PRO-nCOV-3002 study
 - TOP ENROLLER in Malaysia
 - TOP 5th ENROLLER globally
- 3. CYD67 study
 - **TOP ENROLLER** MOH sites in Malaysia
 - Special Education Network in Asia (SENIA) Advocacy Award



CRC HOSPITAL QUEEN ELIZABETH II

Established in December 2011 **TOPING Control 1 | State of the Antical Research Centre 操系研究中心 **TOPING Control 1 | State of the Antical Research Centre 操系研究中心 **TOPING Control 1 | State of the Antical Research Centre 操系研究中心 **TOPING Control 1 | State of the Antical Research Centre 操系研究中心 **TOPING Control 1 | State of the Antical Research Centre 操系研究中心 **TOPING Control 1 | State of the Antical Research Centre 操系研究中心 **TOPING Control 1 | State of the Antical Research Centre 操系研究中心 **TOPING Control 1 | State of the Antical Research Centre 操系研究中心 **TOPING Control 1 | State of the Antical Research Centre 操系研究中心 **TOPING Control 1 | State of the Antical Research Centre 操系研究中心 **TOPING Control 1 | State of the Antical Research Centre 操系研究中心 **TOPING Control 1 | State of the Antical Research Centre 操系研究中心 **TOPING Control 1 | State of the Antical Research Centre 操系研究中心 **TOPING Control 1 | State of the Antical Research Centre | State

HEART FAILURE, CHRONIC RHEUMATIC HEART DISEASE, and MEDICAL DEVICES

Research focus areas:

Certificate of
Excellence 2017
(**TOP 10** CRC
Hospital for ISI
Journal Impact
Factor)

Certificate of
Achievement 2018:
IQVIA preferred
site

Heart Failure (MyHF) Registry

CRC HOSPITAL DUCHESS OF KENT



CRC HOSPITAL TAWAU



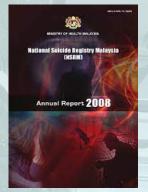
22 YEARS OF ICR EVOLUTION



"To raise new questions, new possibilities, to regard old problems from a new angle, requires creative imagination and marks real advance in science."

-Albert Einstein

Help to establish and/or support 35 disease registries (since 2000)











Established the National Healthcare Statistics Initiative (2005–2013)

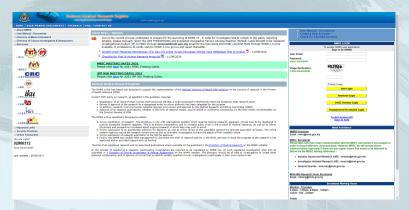








Pioneered the development of the National Medical Research Register (NMRR), with its nationwide roll-out in 2007



Contributed to the Malaysia Health Systems Research (MHSR) 2015–2016



- Quality and Outcomes Framework (QOF)
- Cost Function and Efficiency
- Quality and Cost of Primary Care (QUALICOPC)
- Amenable Mortality
- Enhanced Primary Health Care (EnPHC)

ASEAN Costs in Oncology (ACTION) Study, 2012-2014

- Assess the economic impact of cancer.
- 8 low- and middle-income countries in Southeast Asia.
- 9,513 newly diagnosed cancer patients.
- Research findings utilised in government initiatives: PeKa B40 and MySalam.





RESEARCH ARTICLE

Catastrophic health expenditure and 12-month mortality associated with cancer in Southeast Asia: results from a longitudinal study in eight countries

The ACTION Study Group

Background: One of the biggest obstacles to developing policies in cancer care in Southeast Asia is lack of reliable Association of Southeast Asian Nations (ASEAN) region - the Asean CosTs In ONcology (ACTION) study - to assess the economic impact of cancer

Methods: The ACTION study is a prospective longitudinal study of 9,513 consecutively recruited adult patients with an initial diagnosis of cancer. Twelve months after diagnosis, we recorded death and household financial catastrophe (out-of-pocket medical costs exceeding 30 % of annual household income). We assessed the effect on these two outcomes of a range of socio-demographic, clinical, and economic predictors using a multinomial regression model

outcome of a range of soon-betnographic, clinical, and economic predictors using a mutinomia regression model.

Results: The mean age of participants was 52 years; 64 % were women. A year after diagnosis, 29 % had died,
48 % experienced financial catastrophe, and just 23 % were alive with no financial catastrophe. The risk of dying
from cancer and facing catastrophic payments was associated with clinical variables, such as a mone advanced
disease stage at diagnosis, and sooceconomic status per-diagnosis. Participants in the low income category
within each country had significantly higher odds of financial catastrophe (odds ratio, 5.86; 95 % confidence
inneval, 476–273 and death 65.2 434–70.0 than participants with high income. Those without insurance were
also more likely to experience financial catastrophe (127;1.05–152) and die (1.51;121–1.88) than participants

Conclusions: A cancer diagnosis in Southeast Asia is potentially disastrous, with over 75 % of patients experiencing death or financial catastrophe within one year. This study adds compelling evidence to the argument for policies the improve access to care and provide adequate financial protection from the costs of fileses.

Background
The Association of Southeast Asian Nations (ASEAN)
region consists of ten countries — Brunei, Cambodia,
Indonesia, Laos, Malaysia, Myamar, the Philippica,
Singapore, Thailand, and Vietnam — and is home to over
half a Billion people. The burden of cancer is increase
in the ASEAN region, due to population againg and
growth and the adoption of cancer-associated likely
behaviours [1]. In 2012, there were estimated to be over
Controlled in the ASEAN region, the Controlled in the Controll









Policy and priorities for national cancer control planning CrossMark in low- and middle-income countries: Lessons from the Association of Southeast Asian Nations (ASEAN) Costs in Oncology prospective cohort study



The ACTION Study Group 1 , Nirmala Bhoo-Pathy a,b,* , Cheng-Har Yip c , Sanne A.E. Peters d,c , Merel Kimman d,f , Richard Sullivan g , Stephen Jan d , Mark Woodward d,c , Chiu-Wan Ng a

- Julius Centre University of Malaya, Faculty of Mediche, University of Malaya, 30603 Kusla Lumpur, Malaysisi National Clinical Research Centre, Level 3, Dermatology Block, Kusla Lumpur Hospital, Jalim Pohang, 50586 Kusla ungur, Malaysis Department of Surgery, Subang Juya Medical Centre, 47500 Salangor, Malaysis

Abstract Background: Evidence to guide policymakers in developing affordable and equi-table cancer control plans are scarce in low- and middle-income countries (LMIC). Methods: The 2012—2014 ASEAN Costs in Oncology Study prospectively followed-up-951: newly diagnosed cancer patients from eight LMIC in Southeast Asia for 12 months. Overal meny augmont cancer parameter from egin Lawre. In Soutment Anna for L2 months, Overari and country-specific incidence of finandial catastropted (coul-47-pocket health oss 5 2 30% of annual household income, exonomic hardship (inability to make necessar) where health of the ments), poverty (living below national poverty line), and all-cause mortally were determined. Stepwise multinomial regression was used to estimate the extent to which health insurance, cancer stage and treatment explained these outcomes.

* Corresponding auchor: Julius Centre University of Malaya, Department of Social and Preventive Medicine, Faculty of Medicine, Un Malaya, 5060 Lembali Pantai, Kuala Lumpur, Malayaia, Fax: +60 3 7867 4975.

Emai addresse: ovenits/demail.com.nimala.bhoosenth/dumune.edu.nv (N. Bhoo-Pathy).

http://dx.doi.org/10.1016/j.ejca.2016.12.014 0959-8049/© 2017 Elsevier Ltd. All rights reserved

STORM-C-1 Study (Ravidasvir Trial), 2016-2021

- Collaboration with Drugs for Neglected Diseases initiative (DNDi) and Doctors Without Border (MSF).
- Assess the efficacy and safety of affordable direct-acting antivirals for hepatitis C virus (HCV) infection.
- A national plan to cure chronic HCV infection patients.
- Malaysia: the first in the world to approve Ravida (affordable HCV medicine).

THE LANCET Gastroenterology & Hepatology

ARTICLES | VOLUME 6, ISSUE 6, P448-458, JUNE 01, 2021

Efficacy and safety of ravidasvir plus sofosbuvir in patients with chronic hepatitis C infection without cirrhosis or with compensated cirrhosis (STORM-C-1): interim analysis of a two-stage, open-label, multicentre, single arm, phase 2/3 trial

From the Desk of the Director-General of Health Malaysia

Kenyataan Akhbar KPK 4 Jun 2021 -Kelulusan Pendaftaran Secara Bersyarat Ravidasvir 200mg Tablet Bagi Rawatan **Hepatitis C**

meluluskan pendaftaran bersyarat produk Ravida® Tablet 200mg (Ravidasvir Hydrochloride 200mg) dalam mesyuarat kali ke-358 pada 4 Jun 2021. Malaysia merupakan **negara pertama di duni**a yang meluluskan penggunaan produk Ravida®, yang digunakan secara kombinasi dengan ubat lain untuk merawat jangkitan virus hepatitis C kronik (HCV) dalam kalangan oran vasa. Produk ini dikilangkan oleh Doppel Farmaceutici S.R.L, Itali yang mana Pharmaniaga Manufacturing Berha megang pendaftaran produk tersebut di Malaysia.

2030. Walau bagaimanapun, kos pengesanan dan rawatan menggunakan ubat *Direct Acting Antivirols* (DAA) pada masa ini memerlukan kos yang tinggi. Oleh itu, terdapat keperluan untuk mencari penyelesaian alternatif dalam mendapatkan rawatar wang berkesan dengan kos yang lebih berpatutan. Pelan Istrategik Nasional bag Hepatitis B dan C 2019-2023 tehah yang berkesan dengan kos yang lebih berpatutan. Pelan Istrategik Nasional bag Hepatitis B dan C 2019-2023 tehah dilangunkan oleh KKM untuk merangka hala tuju yang jelas dan memastikan matlamat menghapuskan hepatitis B dan C dapat dicapal.

2016 bagi mengurangkan halangan daripada segi akses dan kemampuan untuk pesakit HCV mendapatkan rawatan di Malaysia. Hasil utama kerjasama ini adalah melalui pelaksanaan Kajian Klinikal HCV DNDi iaitu kajian STORM-C-1 yang Lancet Castroenterology & Hepatology' pada 15 April 2021.

TAN SRI DATO' SERI DR. NOOR HISHAM ABDULLAH

🗽 📵 Efficacy and safety of ravidasvir plus sofosbuvir in patients with chronic hepatitis C infection without cirrhosis or with compensated cirrhosis (STORM-C-1): interim analysis of a two-stage, open-label, multicentre, single arm, phase 2/3

Methods STORM-C-1 is a two-stage, open-label, phase 2/3 single-arm clinical trial in six public academic and no academic centres in Malaysia and four public academic and non-academic centres in Infland, Patients with HCI with compensated cirrhosis (Metatris F and Châld-Turcotte Pugli class A) or without cirrhosis Metatris F and Châld-Turcotte Pugli class A) or without cirrhosis previous interferon-base 18-69 years were eligible to participate, regardless of HCV genotype, HIV infection status, previous interferon-base HCV treatment or source of HCV infection. Once dally revisions (200 Migra dissolvative) desposed year persenthe for 12 weeks for patients without cirrhosis and for 24 weeks for those with cirrhosis. The primary endpoin we assumed voltogical response at 12 weeks after treatment (WRIZ: defined as HCV RAVA 2.12 Ultral. in Thailand as

THY O'-INICIAON, AND 27 (2579) and reviewer (persons interteron-states treatment, are trust continued tradition-temperal adverse enems were previous [25] [1238], cough [679], upper respiratory tract infection [23] [806], and headache [26] [783]. There were no deaths or treatment discontinuations due to serious adverse events related to study and the continued of the continued

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sople have a chronic hepatitis C virus depole have a chronic hepatic C virus depole have a chronic hepatitis control hepatitis contr

COVID-19 Research, 2020-2022

- INCEPTION B: Intent and Perception Towards COVID-19 Booster Vaccination Among Malaysians
- VIGILANCE: Post-COVID-19 Vaccination Immunogenicity Surveillance Among Healthcare Workers
- RECOVAM: The Real-World Evaluation of COVID-19 Vaccines Under the Malaysia National COVID-19 Immunisation Programme
- SafeCoVAC: Case-Based Monitoring of Adverse Events Following COVID-19 Vaccination
- I-TECH: Efficacy of Ivermectin Treatment on Disease Progression Among Adults With Mild to Moderate COVID-19 and Comorbidities
- CODIQ-My: COVID-19 Digital Quarantine and Home Monitoring



regression.

Rembir: Fer BITTEDD, Y. E. against COVID-19 infections declined from 90.88 (95°C O 88.4, 92.1) in the fast group to P3.18 (165°C O 76.1, 12.2) in the tearly group, VE for BITTEDD2 against IOL administor as the part of the part of 150°C O 76.1, 12.2 in the tearly group, VE for BITTED2 against IOL administor was to 150°C O 76.2 in 150°C

COVID-19 describes from 74.55 (195.4 C 710. 78.0)

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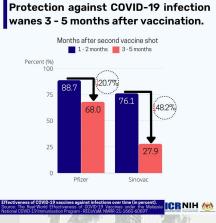
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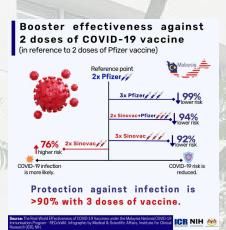
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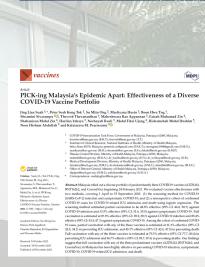
Reproved COVID-19, recoins safety, advans events of special interest (AESB, active surveillance, self-controlled, safety surveillance, real world ovidence

Abbreviations: AER, attense event following immunisation; AESI, advanse event of special interest; COVID19, commerciae.

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"You cannot hope to build a better world without improving the individuals. To that end, each of us must work for our own improvement and, at the same time, share a general responsibility for all humanity, our particular duty being to aid those to whom we think can be most useful."

-Marie Curie







Training and Consultation

Investigator-Initiated Trial (IIT) Workshop

REDCap
Training for
Data
Collection

Critical Appraisal Workshop

Good Clinical
Practice (GCP)
Course

Protocol/ Manuscript Writing Workshop

Research Ethics Workshop

Statistical Workshop

> Research Camp

Effective Oral and Poster Presentation Workshop Training for Clinicians:

- Emergency
- Geriatric
- Psychiatry

Introduction to Clinical Research (ICR) Workshop

National Conference for Clinical Research (NCCR)

A premier annual event since 2007 with invaluable knowledge-sharing and networking opportunities.

A platform for healthcare professionals, policymakers, academics, and industries to interact.

The Dr. Wu Lien-Teh Research Awards: showcase and celebrate the efforts of aspiring researchers in Malaysia.



Minister of Health officiating NCCR 2012 at Putra World Trade Center (PWTC) Kuala Lumpur.



Deputy Director-General of Health (R&TS) signing the NCCR 2009 guest book at G Hotel Penang.

Objectives

- Seek better research options to develop new ventures.
- Discover, discuss, and disseminate clinical research information.
- Build bridges across clinical specialties and research areas.
- Be part of a multidisciplinary community, promoting clinical research in the Asia Pacific region.



Director-General of Health officiating NCCR 2013 at The Royale Chulan Kuala Lumpur.



Director of ICR delivering her speech at NCCR 2020 virtual conference.

NCCR Two Decades of NCCR

| 2007 | Advancing Clinical Research | Promoting Clinical Research in Asia | 2008 |
|------|--|---|------|
| 2009 | Expanding the Range of Clinical Research in Malaysia | Advancing Medical Research: The Next Stage | 2010 |
| 2011 | Trials, Registries, and Databases: Many Angles, One Aim | Novel to Nobel—Better Research, Better Doctors, Better Health | 2012 |
| 2013 | Translate & Transform | Research That Matters | 2014 |
| 2015 | Research Matters to Society | search Matters to Society Big Data Driving Clinical Research for Health | |
| 2017 | Precision Medicine— The Future is Now | Patient-Centred Research: Digital Health | 2018 |
| 2021 | Niche to Norm | Conference of Very Important Disease (C.O.V.I.D) | 2020 |
| | 15 th NATIONAL | | |

CONFERENCE FOR CLINICAL RESEARCH 2022 "Data to Decisions"



"If you can't fly then run, if you can't run then walk, if you can't walk then crawl, but whatever you do you have to keep moving forward."

-Dr. Martin Luther King Jr

ICR Future Research A Quantum Leap



- Personalise
- Predictive
- Preventive
- Participatory

e.g. Gene Therapy and Vaccine Development

- Clinical Trial Hospital with "Bench to Bedside" Concept
- Explore Traditional and Complimentary Medicine in Malaysia





- **Big Data Analytics**
- Internet of Medical Things (IoMT)
- Artificial Intelligence and
 Machine Learning—
 Integration with
 Precision Medicine and
 Clinical Trial Hub

ICR Diversified Workforce

The Researchers

Clinical Specialist
Public Health Specialist
Medical Officer
Pharmacist
Nurse
Research Officer
Research Assistant

Worldwide Qualifications

i. Post-Graduate Clinical Specialty Training

ii. PhD

- Clinical Epidemiology
- Biostatistics
- Microbiology
- iii. Master of Science
- Genetics
- Health Research
- Data Science and Analytics
- Social & Administrative Pharmacy
- iv. Master of Pharmacy
- v. Master of Clinical Research Methods
- vi. Master of Epidemiology (Pharmacoepidemiology)
- vii. Master of Medical Statistics
- vii. Master of Public Health
- ix. Master of Health Economics
- x. Master of International Health Policy
- xi. Master of Information System













"What separates privilege from entitlement is gratitude."

-Dr. Brené Brown

We are grateful to YB Khairy Jamaluddin, the Minister of Health Malaysia for his encouragement towards ICR's growth.

We wish to thank Tan Sri Dato' Seri Dr. Noor Hisham Bin Abdullah, the Director-General of Health Malaysia for the permission to publish this book.

We also wish to extend our gratitude to Datuk Dr. Muhammad Radzi Bin Abu Hassan, the Deputy Director-General of Health (Research and Technical Support); Dr. S. Asmaliza Binti Ismail, the Manager of NIH; and Datuk Dr. Kalaiarasu M. Peariasamy, the Director of ICR for their support in publishing this book.

Our heartfelt appreciation also to everyone at ICR and The Network of CRCs for their contributions to this book.

"During my time at ICR, I learned about the commitment and resilience it takes to be part of a project, being responsible for keeping to timelines, keeping the morale of everyone going, and managing expectations whenever circumstances don't go the way we want them to. My experience also taught me the importance of having a common goal, planning, and communication in achieving objectives. And most importantly, I value the friendship and camaraderie built with fellow colleagues based on respect and transparency. I hope ICR continues to expand the opportunities for those seeking growth outside clinical career pathway."

Dr. Yasmin Wahab Senior Medical Affairs Manager Singapore GlaxoSmithKline Pte Ltd Former ICR Researcher

"I joined ICR from August 2013 until October 2021. The eight years spent working in ICR was a fruitful journey. I was given many opportunities to learn and grow as a healthcare researcher in Malaysia. Most importantly the colleagues in ICR are always kind and helpful. And by working together, we managed to deliver outstanding projects and results that hopefully contributed to the nation. I will always cherish the time I had in ICR and the relationships I built during my time there. I wish ICR more wonderful years ahead, especially in delivering more impactful research to shape a better future of healthcare in Malaysia."

Ong Su Miin
Senior Real-World Evidence (RWE) Research Analyst
CONEXTS, Novartis
Former ICR Researcher

"Congratulations, ICR for a fruitful 22 years! I wish that ICR continues to play a leading role in healthcare research, generating timely and relevant evidence to help our policymakers in advancing our healthcare system. I also would like to thank ICR for all the learning opportunities given. They have certainly helped me in building my skills, deepen my knowledge, and broaden my experience. The experience I have gained in ICR has certainly been one of the most valuable assets in my professional career as well as personal development. Of course, not to forget our team and our leaders whom I truly enjoy working with. I miss the lunchtime chat!"

Dr. Foo Chee Yoong
Associate Principal
IQVIA Health Economics and Outcome Research
Former ICR Researcher

"I had a great experience with ICR during the early stage of my career. I met many amazing colleagues, who are passionate about research and making an impact in policy, from whom I learned much. Thank you, ICR, and Happy 22nd Anniversary! Wishing you and fellow staff members more success and greater heights in the years to come =D"

Dr. Lim Ka Keat

Research Fellow in Health Economics

King's College London

Former ICR Researcher













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MALAYSIA